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NOTICE OF ALLOWANCE AND FEE(S) DUE

3624 7590 08/08/2008

VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADEL PHIA PA 19103 EXAMINER

LOEWE, SUN JAE Y

ART UNIT PAPER NUMBER

1626 DATE MAILED: 08/08/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,386	04/19/2006	Girij Pal Singh	SMC-PT009	3611

TITLE OF INVENTION: NOVEL METHOD FOR PREPARATION OF CRYSTALLINE PERINDOPRIL ERBUMINE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	11/10/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless correcte maintenance fee notifical	correspondence includir ed below or directed oth	or transmitting the 1880 ig the Patent, advance of nerwise in Block 1, by (a	rders and notification of n a) specifying a new corres	naintenance fees wi pondence address;	II be ma and/or (I	niled to the current b) indicating a sepa	correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
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PHILADELPHI.	A, PA 19103						(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTORN	EY DOCKET NO.	CONFIRMATION NO.
10/576,386 TITLE OF INVENTION	04/19/2006 : NOVEL METHOD FO	OR PREPARATION OF C	Girij Pal Singh CRYSTALLINE PERINDO	DPRIL ERBUMINE		MC-PT009	3611
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nonprovisional	NO	\$1440	\$300	\$0		\$1740	11/10/2008
EXAM	INER	ART UNIT	CLASS-SUBCLASS				
LOEWE, S	UN JAE Y	1626	514-419000				
"Fee Address" ind. PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address 12 or more recent) attach ND RESIDENCE DATZ less an assignee is ident h in 37 CFR 3.11. Comp	nge of Correspondence "Indication form ed. Use of a Customer A TO BE PRINTED ON	2. For printing on the p (1) the names of up to or agents OR, alternativ (2) the name of a single registered attorney or a 2 registered patent attor listed, no name will be THE PATENT (print or typ data will appear on the p (7) a substitute for filing an (8) RESIDENCE: (CITY	3 registered patent vely, e firm (having as a sigent) and the name meys or agents. If n printed.	member s of up t o name i	a 2a is 3attified below, the de	ocument has been filed for
Please check the appropr	iate assignee category or	categories (will not be pa	rinted on the patent):	Individual 🚨 Cor	poration	or other private gro	up entity 🚨 Government
4a. The following fee(s): Issue Fee Publication Fee (N Advance Order - 4	o small entity discount p		b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo	d. Form PTO-2038	is attach	ed.	
	s SMALL ENTITY state	is. See 37 CFR 1.27.	☐ b. Applicant is no long				
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than to Office.	he applicant; a regis	tered atte	orney or agent; or th	e assignee or other party in
Authorized Signature				Date			
Typed or printed name				Registration No	o		
This collection of inform an application. Confident submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C tiality is governed by 35 d application form to the ons for reducing this but firginia 22313-1450. DC 13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by th imated to take 12 m idual case. Any cor r, U.S. Patent and T D'THIS ADDRESS.	e public inutes to nments o 'rademar SEND'	which is to file (and o complete, includin on the amount of tir k Office, U.S. Depa TO: Commissioner i	by the USPTO to process) g gathering, preparing, and ne you require to complete utment of Commerce, P.O. for Patents, P.O. Box 1450,

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UNITED PLAZA	, SUITE 1600		ART UNIT	PAPER NUMBER
30 SOUTH 17TH			1626	
PHILADELPHI/	A, PA 19103		DATE MAIL ED. 00/00/200	10

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 167 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 167 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)	
10/576,386	SINGH ET AL.	
Examiner	Art Unit	
SUN IAE V LOEWE	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to 7-15-2008. 2. The allowed claim(s) is/are 1. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - b) \(\subseteq \text{Some* c} \) \(\subseteq \text{None of the:} \) 1. T Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No.
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. T Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. T Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- Other .

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DETAILED ACTION

1. Claim 1 pending in the instant application.

Response to Amendment

The amendments to the claims filed on July 15, 2008 have been fully considered. The 35
USC 112 1st paragraph rejection is obviated, and hereby withdrawn.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance. The instant process of preparing crystalline form of perindopril erbumine (characterized by the XRD pattern of claim 1) using N,N-dimethylformamide, dimethoxymethane, 2,2-dimethoxypropane, or 1,2-dimethoxyethane is novel and non-obvious over the prior art. The closest references teach alternate crystallization solvents, for example, ethyl acetate (WO 01/87835).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusions

- Claim 1 allowed.
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

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Application/Control Number: 10/576,386

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./ 7-28-2008

/Kamal A Saeed, Ph.D./ Primary Examiner, Art Unit 1626